

Remarks

Reconsideration of the claims in view of the response to the previous Office Action is gratefully acknowledged.

Claims 36-41, 43, 44 and 46 are pending in the instant Office Action in which Claims 36-37 are allowed and Claims 38-41, 43, 44 and 46 stand rejected. In response, Claims 38 and 41 (and, implicitly, claims which depend from them) are amended; and Claims 44 and 46 are canceled. No new subject matter is added. In addition, a terminal disclaimer is being provided along with this response. The Examiner is requested to reconsider the application in view of the claim amendments, the terminal disclaimer and the remarks below and to find the claims allowable.

Claims 38-39 are rejected under 35 U.S.C. 102(b) as anticipated by Shirai et al. (Shirai), cited as Document U on the Form PTO-892 in the Office Action. The Shirai paper constitutes accidental anticipation by a species within the scope of the claims. Claim 38 has been amended by the insertion of a proviso to delete the species identified as **(R)-6b** in Shirai to obviate the anticipation. In addition, it is noted that the species identified as **(R)-5b** in Shirai is within the scope of Claim 41; so Claim 41 also is amended by proviso to delete the species identified as **(R)-5b** in Shirai. In view of these amendments, it is believed that there no longer is anticipation under 35 U.S.C. 102(b) with respect to Shirai.

Claims 38-41, 43-44 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting over Claims 1-18, 21-22 and 26-27 of U.S. Patent No. 6,936,611 ('611), cited as Document A on the Form PTO-892 in the Office Action. Except as to Claims 38-39 of the instant application with respect to Claims 21 and 26-27 of '611 and as to Claim 41 of the instant application with respect to Claims 1-18 and 22 of '611, this basis for rejection is respectfully traversed, as discussed below. In view of the overlap of scope of Claims 38-39 of the instant application with respect to the scope of Claims 21 and 26-27 of '611 and of the overlap of scope of Claim 41 of the instant application with respect to Claims 1-18 and 22 of '611, a terminal disclaimer is being submitted along with this response to obviate the ground of nonstatutory obviousness-type double patenting over '611.

As to the traversal noted above, the following is pointed out as to the nature of the claimed compounds. The instant application and '611 are "sibling" applications; application serial no. 10/030,187 is the parent of both. The compounds of Claims 1-18 and 22 of '611 are inhibitors of Factor Xa, useful in the treatment of thrombotic disorders, inter alia; and they all may be considered to be drawn to a compound of Formula (I). The claims of the instant application are drawn to: (a) a process for the preparation of a restricted (by a prior restriction requirement) subset of compounds of Formula (I): Claims 36-37; (b) intermediate compounds useful for that process: Claims 38-40; and (c) N-protected precursors to the intermediates: Claims 41, 43, 44 and 46. The N-protecting group Pg³ of Claim 41 is defined as RCO. Only when R has a value of optionally substituted phenyl is there is overlap between Claim 41 and Claims 1-18 and 22 of '611. Accordingly, the terminal disclaimer is being submitted along with this response to obviate the ground of nonstatutory obviousness-type double patenting over '611. Additionally, there is overlap between the intermediate amine of formula (10) of Claims 38-39 of the instant application and the intermediate amine of Claims 21 and 26-27 of '611. Also, for this reason, the terminal disclaimer is being submitted to obviate the ground of nonstatutory obviousness-type double patenting over '611. Otherwise, it is believed that there is no overlap between Claims 38-40 and 43-44 of the instant application and Claims 1-18 and 22 of '611.

Claims 38-41, 43-44 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting over Claims 1 and 3-11 of U.S. Patent No. 6,855,715 ('715), cited as Document B on the Form PTO-892 in the Office Action. Claims 44 and 46 are canceled. As to Claims 38-41 and 43, this basis for rejection is respectfully traversed. The compounds of Claims 1 and 3-11 of '715 are inhibitors of Factor Xa, mutually exclusive and patentably distinct from those of '611, which also are useful in the treatment of thrombotic disorders. There is no overlap between the definitions of the intermediate compounds of Claims 38-41 and 43 of the instant application and the Factor Xa inhibitors of Claims 1 and 3-11 of '715. The intermediate primary amine of Claims 38-39 has no value of R₂ or X-X; and, further, the substituent on the piperaziny1 nitrogen not attached to L (i.e. R_P) is never the same as any of the claimed values for the substituent on the piperaziny1 nitrogen not attached to L in '715; so there can be no overlap between the instant Claims 38-39 and the claims of '715. The intermediate secondary amine of Claim 40 of the instant application has no substituent on the piperazine nitrogen not attached to L; so there cannot be any overlap with the claims of '715. As to the N-protected amine of Claim 41 (and dependent Claim 43), as noted above, the substituent on the piperaziny1 nitrogen not attached to L (i.e. R_P) is never the same as any of the claimed values for the substituent on

the piperazinyl nitrogen not attached to L in '715; so there can be no overlap between the instant Claim 41 (and dependent Claim 43) and the claims of '715. Claim 44 (along with dependent Claim 46) is canceled to obviate any possible overlap with any claim of '715. Accordingly, there is no obviousness-type double patenting with any of the claims of '715.

The Electronic Patent Application Fee Transmittal form accompanying this response provides authorization to charge any requisite fee (other than the Issue Fee and Publication Fee) to Deposit Account No. 05-0840.

The Examiner is encouraged to call concerning any detail to facilitate prosecution of the application.

Respectfully submitted,

/Thomas E. Jackson/

Thomas E. Jackson
Patent Attorney
Registration No. 33064
Phone: 317/277-3735

Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288

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